FDA/DDM HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

SEP 30 2004

Ref: FDA Docket No. 94V-0306
Accession No. 94A0966-04

Mr. James S. McDaniel
Owner
West Coast Laser Service
P.O. Box 90610
San Bernardino, California 92427

Dear Mr. McDaniel:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of West Coast Laser Service, dated July 19, 2004, for renewal of variance, Number 94V-0306, from 21 CFR 1040.11(c) of the performance standard for laser products is approved. West Coast Laser Services formerly operated under the name Laser-Light Shows and Devices. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. **Variance Number**

94V-0306

B. **Effective Date**

In accordance with 21 CFR 1010.4(c)(1), this variance renewal shall become effective on the date of this letter.

C. **Termination Date**

This variance shall be terminated after December 21, 2006.

D. **Product for Which Variance is Granted**

This variance is granted for Class IV laser light shows assembled and produced by West Coast Laser Service. The shows will be produced with certified Mirage Productions models MR-10-AK005 and MR-10-AH250 laser projection systems containing certified argon and krypton lasers. The firm may also build and assemble such systems in nightclubs for lease in accordance with Condition 4 of Attachment A of this variance.

The laser light shows will be produced in any type of facility or outdoor, unenclosed area for less than five days. The effects employed may be front or rear screen projection, holographic displays, multiple reflection/diffraction effects, reflections from stationary mirrors, fiber optic projections, and enhanced scattering effects.

E. **Provision from Which Variance is Granted**

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product. This section also prohibits human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

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**F. Conditions under Which Variance is Granted**

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A and Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

**G. Basis for Approval of Variance**

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, and by warnings in the user/purchaser information.

**H. Certification Label**

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 96V-0306 effective December 21, 1994.

This variance action is available for public disclosure in the Food and Drug Administration (FDA) Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Division of Dockets Management, Docket No. 94V-0306

Attachments A and B